K120869



OCT 25 2012

| 510(k) Summary: AVS® Anchor-L Lumbar Cage System | |
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| Submitter: | Stryker Spine<br>2 Pearl Court<br>Allendale, New Jersey 07401 |
| Contact Person | Tiffani Rogers<br>Manager, Regulatory Affairs<br>Phone: 201-760-8206<br>Fax: 201-760-8406<br>Email: tiffani.rogers@stryker.com |
| Date Prepared | August 2, 2012 |
| Trade Name | AVS® Anchor-L Lumbar Cage System |
| Common Name | Intervertebral Fusion Device |
| Proposed Class | Class II |
| Classification Name and Number | Intervertebral body fusion device, 21 CFR 888.3080 |
| Product Code | OVD, MAX |
| Predicate Devices | The AVS® Anchor-L System was shown to be substantially equivalent to the devices listed below:<br>• Medtronic *SOVEREIGN* (K110063)<br>• Surgicraft *STALIF TT* (K073109)<br>• Stryker Spine *AVS PL* (K073470 & K082014) |
| Device Description | The AVS® Anchor-L Lumbar Cage System is a hollow, rectangular-shaped PEEK Optima® cage with three tantalum markers. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints, and lordotic angles to adapt to varying patient anatomies. The PEEK Optima® cage portion consists of two closed pockets for graft containment and has serrations on the superior and inferior surfaces of the cage. When without additional supplemental fixation, the Anchor-L Lumbar Cage designed to be used |

K120869



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| | exclusively with the internal supplemental fixation provided (AVS® ANCHOR-L Fixation Screws and Clip Plate). |
| Intended Use and Indications for Use | The Stryker Spine AVS® Anchor-L is an intervertebral body fusion device indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.<br><br>DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.<br><br>The AVS® Anchor-L Lumbar Cage System is to be implanted via an open, anterior approach.<br><br>The AVS® Anchor-L Lumbar Cage System may be used as an intervertebral device with integrated fixation or in conjunction with supplemental fixation. When used as an intervertebral device with integrated fixation, the AVS® Anchor-L Lumbar Cage must be used with the three internal screws and plate fixation provided by AVS® Anchor-L Fixation Screws and Clip Plate. If AVS® Anchor-L is used with less than three or none of the provided screws, additional supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine must be used to augment stability. The accompanying Clip Plate must be used anytime the device is used with any number of screws. |

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| Summary of the Technological Characteristics | The subject AVS® Anchor-L implant system and the predicates share similar design features:<br>• Graft windows for packing autogenous bone<br>• Serrations on the superior and inferior surfaces<br>• Comparable heights, widths, depths, and lordotic angles<br><br>Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS® Anchor-L Lumbar Cage System and demonstrated substantially equivalent performance to the identified predicate device systems.<br>The following mechanical tests were performed:<br>• Static Compression (per ASTM F2077)<br>• Dynamic Compression (per ASTM F2077)<br>• Static Compression Shear (per ASTM F2077)<br>• Dynamic Compression Shear (per ASTM F2077)<br>• Static Torsion (per ASTM F2077)<br>• Dynamic Torsion (per ASTM F2077)<br>• Expulsion (per ASTM F04-25-02-02 Draft)<br>• Subsidence (per ASTM F2267) |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Spine
% Ms. Tiffani Rogers
Manager, Regulatory Affairs
2 Pearl Court
Allendale, New Jersey 07401

OCT 25 2012

Re: K120869
Trade/Device Name: Stryker Spine AVS® Anchor-L Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: October 11, 2012
Received: October 12, 2012

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K120869

Device Name: Stryker Spine AVS® Anchor-L Lumbar Cage System

Indications For Use:

The Stryker Spine AVS® Anchor-L Lumbar Cage System is an intervertebral body fusion device indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The AVS® Anchor-L Lumbar Cage System is to be implanted via an open, anterior approach.

The AVS® Anchor-L Lumbar Cage System may be used as an intervertebral device with integrated fixation or in conjunction with supplemental fixation. When used as an intervertebral device with integrated fixation, the AVS® Anchor-L Lumbar Cage must be used with the three internal screws and plate fixation provided by AVS® Anchor-L Fixation Screws and Clip Plate. If AVS® Anchor-L is used with less than three or none of the provided screws, additional supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine must be used to augment stability. The accompanying Clip Plate must be used anytime the device is used with any number of screws.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices